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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,842	05/15/2006	Lorenzo A Pinna	2503-1169	9682
<small>465 7590</small> YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314			<div>EXAMINER</div> <div>GRUN, JAMES LESLIE</div>	
			<div>ART UNIT</div> <div>1641</div>	<div>PAPER NUMBER</div>
			<div>NOTIFICATION DATE</div> <div>11/10/2009</div>	<div>DELIVERY MODE</div> <div>ELECTRONIC</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

### Office Action Summary

**Application No.**

10/547,842

**Applicant(s)**

PINNA ET AL.

**Examiner**

JAMES L. GRUN

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,15,16,19 and 20 is/are allowed.
- 6) ☒ Claim(s) 5-10,12-14 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The amendment filed 16 July 2009 is acknowledged and has been entered. Claims 2, 11, and 17 have been cancelled. Claims 1, 3-10, 12-16, and 18-20 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10, 12-14, and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5 and claims dependent thereupon, it is not clear what applicant intends as encompassed because the sequence of the functional derivative is not clear because there is no "SEQ ID NO: 6" in the sequence listing; it is believed -- SEQ ID NO: 5-- was intended.

Claim 10 and claims dependent thereupon are incomplete because essential steps are omitted, such omission amounting to a gap between the steps and providing no nexus between incubating with candidate compound and identification of compounds that modulate activity. See MPEP § 2172.01.

In claim 12 and claims dependent thereupon, recitations of "the" ALK-modulating activity and same conditions lack antecedent basis.

In claim 14, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where

broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim recites the broad recitation “halogen”, and the claim also recites “preferably chlorine” which is the narrower statement of the range/limitation.

In claim 18, “the” treatment lacks antecedent basis.

Applicant's arguments filed 16 July 2009 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Zimmermann (WO 99/02532).

Zimmermann teaches staurosporine derivative compounds essentially as instantly claimed (see e.g. pages 2-20). The compounds are taught for treatment of tumors.

Applicant's arguments filed 16 July 2009 with respect to the claims have been fully considered. However, with regard to the instantly rejected claim the arguments are considered moot in view of the new ground(s) of rejection set forth above.

Claims 1, 3, 4, 15, 16, 19, and 20 are currently free of the prior art of record and are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Meggio et al. (Eur. J. Biochem. 234: 317, 1995) teach the susceptibility of a majority of protein kinases tested to staurosporine inhibition.

Sausville et al. (J. Clin. Oncol. 19: 2319, 2001) teach treatment of at least one patient with an *alk*-positive anaplastic large-cell lymphoma with a staurosporine derivative.

Kanai et al. (US 6,806,266) teach derivatives of staurosporine as antitumor agents.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./

James L. Grun, Ph.D.

Examiner, Art Unit 1641

November 6, 2009

/Ann Y. Lam/

Primary Examiner, Art Unit 1641

November 5, 2009